STEMCELLS INC

The discovery and development of stem cell therapeutics

Industry & Stem Cells in California

CIRM

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Martin McGlynn

President and CEO

Who Are We?

- Public (Nasdaq: STEM); Small Cap Valuation: $185M
- 60K sq. ft., leased lab/office facility in Palo Alto, CA
- 50 employees; annual payroll ~$6 million
- Founded in 1995 (Weissman; Gage; Anderson)
- Virtual for almost 3 years: $$$$$$$$
- Merged with Cytotherapeutics in 1997
- Name changed to “StemCells Inc.” in 2000
- Burned ~ $66.5M and raised ~$115M since then
- $64M cash balance; burn~$1.5M/month

What Do We Do?

- Regenerative medicine → cell-based therapeutics
- Search for rare cells in donated human organ tissue
- 3 human cell types identified to date:
  - Neural stem cell (HuCNS-SC™)
  - Liver engrafting cell (long term survival)
  - Candidate insulin producing cell
- HuCNS-SC:
  - Robust process to grow billions of cells ex vivo
  - Product: "cells in a bottle"
  - Potential uses in treating many CNS disorders
  - Phase I clinical trial in NCL initiated at OHSU

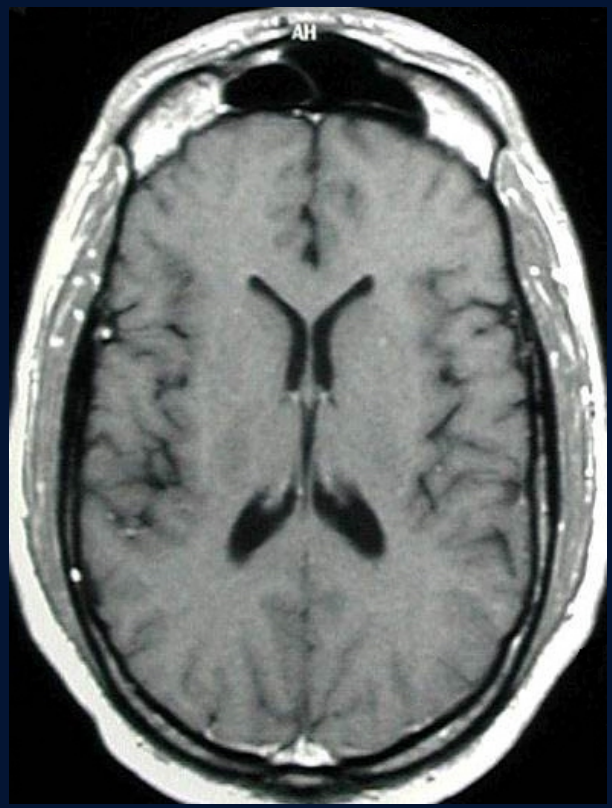
Initial Clinical Applications: Neuroprotection

- Via delivery of missing enzymes in lysosomal storage diseases (LSDs) affecting CNS
  - HuCNS-SC produce LSD enzymes – 5 confirmed to date
  - Proof of concept - Batten mouse model
- Via remyelination
  - Proof of concept – restoration of motor function in spinal cord injury mouse model

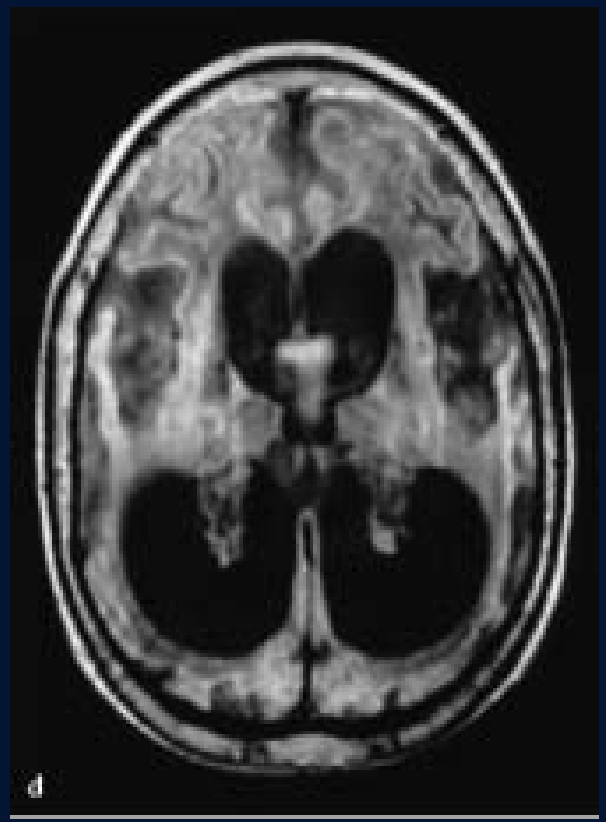
Batten Disease

- Group of fatal genetic disorders affecting infants and young children (neuronal ceroid lipofucinosis or NCL)
- Lack of lysosomal enzyme causes buildup of toxic cellular waste and progressive loss of neurons
- Progressive cognitive and motor deterioration, blindness, seizures and early death
- No therapy

MRI of End Stage Batten Brain



Normal Human Brain



7 yr old Batten child

Vanhanen, S. et al, Neuropediatrics 35:27-35, 2004

Phase I Clinical Study: Batten Disease

- Protocol
  - Six **Patients** with either INCL or LINCL
  - Open label; high and low dose cohorts
  - HuCNS-SC injected directly into brain
  - One year immunosuppression and follow-up
- Primarily for safety
- Preliminary efficacy: development, cognition, communication and behavior
- Anticipate dosing first patient in Q3 2006
- Approximately 2 years to complete trial

Challenges: Organ Derived Stem/Progenitor Cell Approach

- May not exist in every organ: “needle in haystack”
- ~ 9 identified to date; only 3 demonstrated long term engraftment {MSC; HSC; NSC}
- Slow, tedious, expensive to characterize
  - {NSC isolated in 1999; first IND approved in 2005}
- MSC,NSC expandable ex vivo; HSC is not
- Tissue must be sourced to meet cGTP
- Lack of well characterized, predictive, animal models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